UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,357	01/18/2007	Simon Joseph Philip Saul	0635-0057	5449

26568 7590 08/28/2009

COOK ALEX LTD
SUITE 2850
200 WEST ADAMS STREET
CHICAGO, IL 60606

EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
08/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,357	SAUL ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *8-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/20/08,1/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-46 are pending. Claims 1-8 are considered on the merits. Speices election of lipase is acknowledged. Claims 9-46 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Applicant's election of Group I in the reply filed on 6/29/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Double Patenting

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-37 of copending Application No.12/297024. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are coextensive and overlapping in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 1, 5, 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 indicates that a "biological catalyst" is employed. This term is indefinite because it cannot be determined if the biological catalyst is intended to be limited to a catalyst of biological origin. The dependent claims recite the use of enzymes and abzymes, which are a type of enzyme, which imply that the biological catalyst is of biological origin. Please amend claim 1 to clearly recite enzymes or abzymes.

Claim 5 states that the enzyme is part of a whole cell culture. This claim is not clear because it cannot be understood if applicants are attempting to claim that the enzyme is from a microbe or animal. Also unclear is if the intact cell is meant to be a part of the reaction or if just the enzyme which is obtained from a microbial or animal culture is in the reaction mixture. It is noted that upon clarification of this claim, if it reads on the incorporation of an intact mammalian or other higher animal cell, a scope of enablement rejection may be instituted as there do not appear to be any examples in the literature which use intact higher animal cells to catalyze these types of reactions. What is unknown is unpredictable by definition. Please be careful not to add new matter. Please point to the place in the as-filed specification where support for any amendment exists.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/13098 [3].

The claims are directed to an enzymatic catalytic process comprising reacting a substrate with a biological catalyst (lipase has been elected) in a solvent comprising at least one hydrofluorocarbon and water in a concentration less than saturation of the hydrofluorocarbon (one phase) to stereoselectively form a product.

The reference is relied upon as explained below.

WO 99/13098 discloses a process of enzymatic deacylation of benzylpenicillin to 6-aminopenicillanic acid in a solvent comprising water and a non-aqueous solvent which preferably comprises carbon, fluorine and hydrogen only (page 6, l. 14-15). Because benzylpenicillin and 6-

aminopenicillanic acid have optical isomers and are one enantiomer, the transformation of benzylpenicillin to 6-aminopenicillanic acid has an enantiomeric excess of greater than 50%. Example 1, (ii) uses 1-2kg pytosol A with water 100ml as the solvent in the enzymatic deacylation of Pen-G to 6-APA.

This reference, although not specifically directed to the elected species, lipase, is employed to show that the present claims directed to the use of biological catalyst or enzyme or hydrolase are clearly not allowable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/42687 [2] in light of Beier *et al.* [U].

The claims are directed to an enzymatic catalytic process comprising reacting a substrate with a biological catalyst (lipase has been elected) in a solvent comprising at least one hydrofluorocarbon and water in a concentration less than saturation of the hydrofluorocarbon (one phase) to stereoselectively form a product.

The references are relied upon as explained below.

WO 98/42687 discloses the use of trifluoromethane (page 24, l.5) as a solvent in lipase catalyzed stereochemical reactions (abstract).
While there is no mention of the water content of the reaction, lipase preparations always contain some water as explained by Bier *et al.*, page 1680, first column, second paragraph.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/42687 [2], Bier *et al.* [U] as applied to claims 1-4, 7 above, and further in view of Janda *et al.* [V].

The claims are further directed to the use of an abzyme as the biological catalyst.

Janda *et al.* disclose that abzymes (catalytic antibodies) are known having acyl transfer and peptide cleavage activities among others.

It would have been obvious to substitute an abzyme for the enzyme disclosed in the process of WO 98/42687 because Janda *et al.* teach that such catalytic antibodies can be engineered to have lipase, protease, oxidoreductase and other activities. Thus, one of skill in the art may create an abzyme with the desired characteristics in the absence of evidence to the contrary.

Claims 1-5, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/13098 [3] in combination with Smidt *et al.* [W].

The claims and the reference have been discussed above. Claim 4 is directed to the use of enzymes with lipase catalyzing activity.

WO 99/13098 states that the enzyme used in the reaction is preferably capable of catalyzing a deacylation reaction (page 3, l 30).

Smidt *et al.* teach that lipase can stereospecifically deacylate amines.

Lipase is known to be capable of both O deacylation and N deacylation, therefore, lipase type enzymes are encompassed by the generic disclosure.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/13098 [3] and Smidt *et al.* [W] as applied to claims 1-5, 7 above, and further in view of Janda *et al.*[V].

Janda *et al.* has been discussed above.

It would have been obvious to substitute an abzyme for the enzyme disclosed in the process of WO 99/13098 because Janda *et al.* teach that such catalytic antibodies can be engineered to have lipase, protease, oxidoreductase and other activities. Thus, one of skill in the art may create an abzyme with the desired characteristics in the absence of evidence to the contrary.

Claims 1-5, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,925,790 [A] and Ferraboschi *et al.* [X].

The claims have been discussed above.

US 4,924,790 disclose the use of trifluoromethane (col. 2 l. 61) as a reaction solvent for enzymatic reactions. Water will be present in the reaction mixture (col. 2, l. 49). Any enzyme may be used which include those useful in the production of pharmaceuticals (col. 3, l. 20) particularly with steroids (col. 3, l. 27). Thus, since reactions with enzymes commonly include stereospecific reactions, this generic disclosure inherently invites stereospecific enzymatic reactions.

Ferraboschi *et al.* disclose the use of a lipase in a stereospecific resolution of a steroid, 26-hydroxycholesterol, which has both R and S epimers.

The substitution of the hydrofluorocarbon solvent, trifluoromethane as disclosed in US 4,925,790 for the solvent in the lipase catalyzed reaction of

Ferraboschi *et al.* would have been obvious because US 4,925,790 specifically invites the use of the hydrofluorocarbon solvent.

With regard to the limitation "enantiomeric success greater than 50%", in the absence of specifics of the reaction is merely a desired result and thus has little patentable weight in the instant recitations.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,924,790 [A] and Ferraboschi *et al.* [X] as applied to claims 1-5, 7 above, and further in view of Janda *et al.* [V].

Janda *et al.* has been discussed above.

It would have been obvious to substitute an abzyme for the enzyme disclosed in the process of US 4,924,790 [A] because Janda *et al.* teach that such catalytic antibodies can be engineered to have lipase, protease, oxidoreductase and other activities. Thus, one of skill in the art may create an abzyme with the desired characteristics in the absence of evidence to the contrary.

One of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting

claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651